

## Journal of Advanced Medical and Dental Sciences Research

@Society of Scientific Research and Studies

NLM ID: 101716117

Journal home page: www.jamdsr.com

doi: 10.21276/jamdsr

Index Copernicus value = 85.10

(e) ISSN Online: 2321-9599;

(p) ISSN Print: 2348-6805

### Original Research

#### To compare the effectiveness of octenidine dihydrochloride and saline dressing in treating diabetic foot ulcers

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#### ABSTRACT:

**Aim:** To compare the effectiveness of octenidine dihydrochloride and saline dressing in treating diabetic foot ulcers.

**Material and methods:** This research was a prospective comparative investigation carried out at the Department of General Surgery, after the permission of the protocol review committee and institutional ethics committee. All patients with diabetic foot ulcers lasting longer than 6 weeks, who expressed their willingness to participate in the trial. All patients were provided with a comprehensive discussion of the approach, risks, advantages, outcomes, and any issues related with the treatment. This research comprised a total of 200 patients, including 100 individuals in each arm of the Octenidine dihydrochloride dressing group and the Saline dressing group. **Results:** The average surface area of the wound in the saline group was as follows: at baseline it was 11.01 sq.cm, in the 2nd week it was 10.22 sq.cm, in the 4th week it was 9.69 sq.cm, and in the 6th week it was 8.22 sq.cm. In contrast, in the octenidine dihydrochloride group, the average surface area of the wound was 12.42 sq.cm at baseline, 10.22 sq.cm in the 2nd week, 7.36 sq.cm in the 4th week, and 5.49 sq.cm in the 6th week (as shown in table 2). After a duration of 6 weeks, the octenidine dihydrochloride dressing group exhibited a greater average decrease in wound surface area compared to the saline dressing group. These findings are statistically significant, with a p-value of less than 0.05. **Conclusion:** Our findings indicate that the Octenidine dihydrochloride dressing is superior to the saline dressing in promoting expedited wound healing, avoiding infections, and reducing morbidity in patients with chronic diabetic foot ulcers. Moreover, the Octenidine dihydrochloride dressing has a wide range of antimicrobial properties, effectively targeting the biofilm that often develops in individuals with diabetes.

**Keywords:** Octenidine dihydrochloride, Saline, Diabetic foot ulcers

Received: 13 December, 2020

Accepted: 16 January, 2021

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**This article may be cited as:** Kumar A, Nagori S. To compare the effectiveness of octenidine dihydrochloride and saline dressing in treating diabetic foot ulcers. J Adv MedDent Scie Res 2021;9(2): 174-177.

#### INTRODUCTION

Foot ulcers are a prevalent and debilitating illness in those with diabetes, with a worldwide occurrence rate of 6.3%. Male individuals have a higher propensity to develop a diabetic foot ulcer (DFU) compared to females, and those with type 2 diabetes are at a higher risk than those with type 1 diabetes[1]. Diabetic foot ulcers (DFUs) detrimentally affect patients' quality of life, elevate the likelihood of infection and amputation, and impose a significant financial burden on healthcare providers[2-4]. Annually, around 2-2.5% of individuals with diabetes experience the development of a diabetic foot ulcer (DFU). The

estimated cost of foot ulceration and amputation in England in 2014-15 was £1 billion, and it is projected to increase in the future[5]. Therefore, it is crucial to rapidly detect and treat DFUs in order to enhance patient outcomes and alleviate financial burdens on healthcare providers. The prevailing risk factors for diabetic foot ulcers (DFU) The presence of biofilms and infection may potentially influence the pace of wound healing. The term "bio burden" refers to the quantity of live microorganisms that may be found on a surface. Heightened microbial load has been suggested as a significant indicator of unfavourable healing results[6,7]. Microorganisms, such as bacteria,

fungus, and protists, have the ability to transition from individual, mobile cells to a cohesive group of cells called a biofilm. This transition occurs via the processes of adhesion, growth, and division. Established biofilms are enveloped by a defensive matrix, rendering them resistant to eradication by antibiotics, antiseptics, and disinfectants. A minimum of 60% of chronic wounds include a biofilm[8,9]. If not appropriately controlled, their presence may impede wound healing and serve as a prelude to infection[8,9]. Octenidine dihydrochloride is an antibacterial agent that effectively kills a wide range of microorganisms and has not been shown to have any resistance from these microorganisms. This drug is both safe and effective in inhibiting bacterial growth[10]. This medication is well tolerated, devoid of any adverse effects, and does not undergo systemic absorption. Octenidine has deodorising qualities, exhibits action within a just 60 seconds, and maintains its biocidal efficacy for a minimum of 48 hours. The octenilin® wound irrigation solution is a transparent, non-alcoholic solution that contains octenidine. It is specifically formulated to wash and hydrate persistent wounds and burns. Research has shown that octenilin® may effectively prevent the development of biofilm material for a duration of 3 days[10]. Additionally, it may be used to dislodge hardened dressings and purify inaccessible regions, such as narrow crevices and wound cavities[11]. The octenilin® irrigation solution includes ethylhexylglycerin, which has surfactant, emollient, skin-conditioning, and antibacterial characteristics. Ethylhexylglycerin decreases the force between molecules at the surface of water-based solutions, hence improving its ability to spread and adhere to surfaces[10]. Ethylhexylglycerin enhances the distribution of octenilin® irrigation solution across all wound crevices. This research aimed to assess the efficacy of octenidine dihydrochloride dressing and saline dressing in the healing process of diabetic foot ulcers.

## MATERIAL AND METHODS

This research was a prospective comparative investigation carried out at the Department of General Surgery, after the permission of the protocol review committee and institutional ethics committee. All patients with diabetic foot ulcers lasting longer than 6 weeks, who expressed their willingness to participate in the trial. The research only included wounds that were clinically clean and showed no symptoms of

acute inflammation. The research excluded patients with cellulitis/active wound infection, venous insufficiency, venous ulcers, and a prior history of autoimmune illness.

## METHODOLOGY

All patients were provided with a comprehensive discussion of the approach, risks, advantages, outcomes, and any issues related with the treatment. This research comprised a total of 200 patients, including 100 individuals in each arm of the Octenidine dihydrochloride dressing group and the Saline dressing group. These patients had complaints of persistent diabetic foot ulcers (DFU). One group of patients received frequent wound dressings using octenidine dihydrochloride topical cream, while the other group received saline dressings. The wounds were periodically evaluated to monitor their healing status during the research period.

## RESULTS

A total of 200 participants, including 100 in each group (octenidine dihydrochloride group and saline group), successfully completed the follow-up period. Out of the 200 individuals, 149 (74.5%) were male and 51 (25.5%) were female. Both groups had a higher proportion of men, with 70% of the octenidine dihydrochloride group and 79% of the saline group being male. The average age in the octenidine dihydrochloride group was  $58.85 \pm 3.85$ , whereas in the saline dressing group it was  $57.55 \pm 3.96$ . Approximately 50% of individuals in the octenidine dihydrochloride group and 48% in the saline group reported being smokers. Additionally, 41% of individuals in the octenidine dihydrochloride group and 34% in the saline group reported using alcohol. For statistical analysis, the haemoglobin (Hb) levels were considered among the blood investigations conducted. The average haemoglobin (Hb) level in the octenidine dihydrochloride group was  $10.77 \pm 1.26$  gm%, whereas in the saline group it was  $11.65 \pm 1.39$  gm%. The average duration of diabetes was  $10.45 \pm 1.58$  years in the octenidine dihydrochloride group and  $10.33 \pm 1.69$  years in the saline group. The average length of chronic wounds was 8.5 months in the octenidine dihydrochloride group and 9.5 months in the saline group. Both groups had similar demographic features, behaviours, lab investigations, length of diabetes, and duration of chronic diabetic foot ulcer, as shown in Table 1.

**Table 1: Basic parameter of the participants**

Parameter	Octenidine dihydrochloride dressing		Saline dressing	
	Number / Mean	Percentage	Number / Mean	Percentage
Age	$58.85 \pm 3.85$		$57.55 \pm 3.96$	
Gender				
Male	70	70	79	79
Female	30	30	21	21
Smoking	50	50	48	48

Alcohol	41	41	34	34
Duration				
Diabetes (in years)	10.45±1.58		10.33±1.69	
DFU (in months)	8.5		9.5	
Hemoglobin	10.77±1.26		11.65±1.39	

A comparison was conducted between the results of the octenidine dihydrochloride dressing group and the saline dressing group in terms of the decrease in surface area of wounds. The average surface area of the wound in the saline group was as follows: at baseline it was 11.01 sq.cm, in the 2nd week it was 10.22 sq.cm, in the 4th week it was 9.69 sq.cm, and in the 6th week it was 8.22 sq.cm. In contrast, in the octenidine dihydrochloride group, the average surface

area of the wound was 12.42 sq.cm at baseline, 10.22 sq.cm in the 2nd week, 7.36 sq.cm in the 4th week, and 5.49 sq.cm in the 6th week (as shown in table 2). After a duration of 6 weeks, the octenidine dihydrochloride dressing group exhibited a greater average decrease in wound surface area compared to the saline dressing group. These findings are statistically significant, with a p-value of less than 0.05.

**Table 2: Comparison between outcomes of Octenidine dihydrochloride dressing group and saline dressing group in terms of reduction in surface area of wound**

surface area reduction of wounds	Octenidine dihydrochloride dressing	Saline dressing
Baseline	12.42 sq.cm	11.01 sq.cm
2nd week	10.22 sq.cm	10.22sq.cm
4th week	7.36 sq.cm	9.69 sq.cm
6th week	5.49sq.cm	8.22 sq.cm

## DISCUSSION

Octenidine dihydrochloride is a newly developed chemical consisting of two pyridine rings, which was first presented over two decades ago. It has efficacy in combating both gram-positive and gram-negative bacteria[12]. There is currently no evidence of microbial resistance to this substance, and it is generally well tolerated without any observed adverse effects. In a prospective randomised research conducted by Eisenbeiss et al.[13], it was shown that the use of a placebo dramatically reduced microbial colonisation in patients with superficial skin transplant donor site wounds. The objective of wound dressing is to create an environment that is conducive to healing by maintaining a clean wound with a minimal amount of germs present[14]. In our research, the average surface area of the wound in the saline group was as follows: at baseline, it was 11.01 sq.cm, at the 2nd week it was 10.22 sq.cm, at the 4th week it was 9.69 sq.cm, and at the 6th week it was 8.22 sq.cm. In contrast, in the octenidine dihydrochloride group, the average surface area of the wound was: at baseline, it was 12.42 sq.cm, at the 2nd week it was 10.22 sq.cm, at the 4th week it was 7.36 sq.cm, and at the 6th week it was 5.49 sq.cm. After a duration of 6 weeks, the octenidine dihydrochloride dressing group exhibited a greater average decrease in wound surface area compared to the saline dressing group. These findings are statistically significant with a p-value of less than 0.05. Various authors have conducted studies on a wide range of dressings for diabetic foot ulcers (DFU) [15]. DFUs exhibit distinct characteristics, including a poly-microbial nature of infection, reduced tissue vascularity, loss of feeling, and the possibility for deep-seated infection[16]. Octenidine dihydrochloride, when used with

debridement and systemic antibiotics in biofilm-based wound care, effectively controls the presence of microorganisms in chronic wounds and promotes accelerated healing.

## CONCLUSION

Our findings indicate that the Octenidine dihydrochloride dressing is superior to the saline dressing in promoting expedited wound healing, avoiding infections, and reducing morbidity in patients with chronic diabetic foot ulcers. Moreover, the Octenidine dihydrochloride dressing has a wide range of antimicrobial properties, effectively targeting the biofilm that often develops in individuals with diabetes. Therefore, Octenidine dihydrochloride dressing is the favoured choice for chronic DFU patients compared to saline dressing.

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